JUN 2 5 2003

K014013

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510(k) Summary

Applicant's Name and Address

H&W Technologies, LLC
P.O. Box 20281
Rochester, New York 14602-0281

Contact Person, Telephone, FAX

Charles O. Hancock, RAC
Director, Regulatory Affairs

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Submission Date

November 29, 2001

Trade Name

H & W Technology Hospital Ethylene Oxide Sterilizer Control System

Common Name

Hospital Ethylene Oxide Sterilizer Control System

Classification Name

Hospital Ethylene Oxide Sterilizer

Device Classification

Class II (performance standards)
(as per 21CFR, part 880.6860 equivalent device)

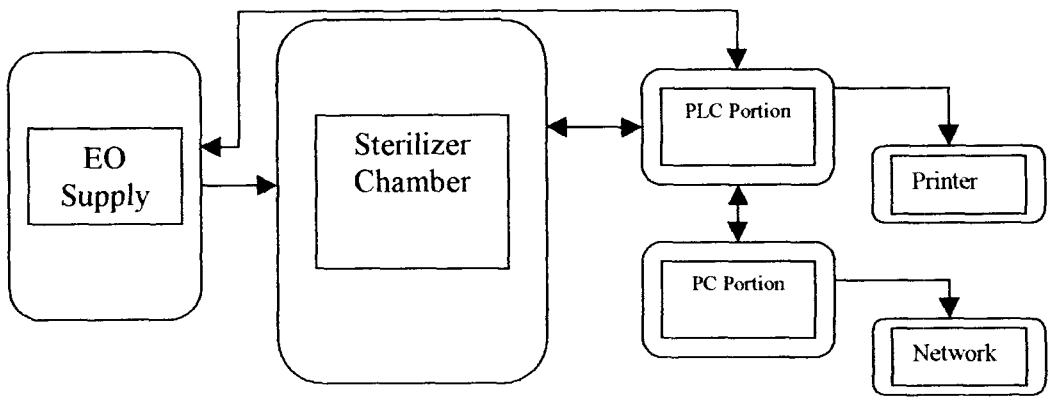
Legally Marketed Equivalent Device Name(s)

Joslyn EO Sterilizer/EO Modernization Kit (K901146)

Description of Device

This device is an accessory to an electronic ethylene oxide sterilizer control system. This control system is a modern, programmable logic controller (PLC)-based system with

Personal Computer (PC) user interface. This accessory control system uses a PLC and a Visual Basic/Windows® user interface. These two features, a PLC for control and a Windows®-based user interface provide multiple advantages. First being the inherent safety and reliability of the PLC and second the operator's ease of use of the Windows®-based user interface. This accessory control system kit is intended for the retrofit of existing sterilizers or for use on sterilizers remanufactured by original equipment manufacturers, third party remanufacturers or their licensees.



Statement of Intended Use

The H & W Hospital Ethylene Oxide Sterilizer Control System is an electronic control system accessory for the retrofit of existing sterilizers to provide operator and information monitoring capabilities of a Personal Computer (PC) together with the functional reliability, safety, and dependability of a programmable logic controller (PLC). Hospital EO sterilizers are dedicated purpose sterilizers with preselected process parameters programmed to allow operation only within very stringent limits in a fixed cycle. The automated cycle performs in such a manner as to assure the repeatability of the process. The predetermined cycles duplicate the cycles provided by the original equipment manufacturer and are demonstrated to deliver the biological performance as stipulated in the consensus standard ANSI/AAMI ST-24.

The H&W system is shown to be developed using a Product Development Life Cycle (PDLC) procedure assuring the integrity of the design process to yield predetermined results. H&W employs a PDLC intended to assure that requirements are defined; design

is controlled; fabrication is in accordance with documentation; testing in conducted so as to validate that the requirements have been met; the product is installed properly; the product is operated per instructions; the product is maintained properly; and the documentation system is maintained over the life of the product. Conformity to the consensus standard is one of the requirements.

Effectiveness

Discussion:

This control system accessory is an electronic control system for the retrofit of existing sterilizers. These controls were originally designed for use with industrial sterilizers where the flexibility to program a number of different process parameters was important. Hospital EO sterilizers are dedicated purpose sterilizers with preselected process parameters programmed to allow operation only within very stringent limits in a fixed cycle. The automated cycle performs in such a manner as to assure the repeatability of the process. The predetermined cycles duplicate the cycles provided by the original equipment manufacturer and are demonstrated to deliver the biological performance as stipulated in the consensus standard.

The predicate Joslyn accessory kit system was shown to be designed to render the same biological kill performance as that of the sterilizer systems it was designed to replace as evidenced by testing in conformance with the requirements of AAMI standard. The H&W system is shown to be developed using a rigorous Product Development Life Cycle (PDLC) procedure assuring the integrity of the design process to yield predetermined results. H&W employs a PDLC procedure intended to assure that: requirements are defined; design is controlled; fabrication is in accordance with documentation; testing in conducted so as to validate that the requirements have been met; the product is installed properly; the product is operated per instructions; the product is maintained properly; and the documentation system is maintained over the life of the product. Conformity to the consensus standard is one of the requirements.

Human factors were not an explicit requirement of the predicate device. However, good hospital practice did dictate ease of use. The state of maturity of the user market for hospital sterilizer controls dictated minimally expected operator interface capability. The H&W system includes not only user expectations in the requirements criteria but also includes the satisfaction of the consensus standard elements along with the flexible features available by employing a PC as the operator control interface. (Information can be presented effectively according to the appropriateness of a given operator response. (For example – attention may be gained by a combination of sound, color, animation or frequency of display as appropriate to the importance and necessity of action.)

Performance is assured in both the predicate system and the H&W system by validating the performance of the system, on-site in a sterilizer with known and already defined characteristics. These characteristics are addressed in the reference standard. The bench mark to be used was and is the sterilizer retrofitted. That sterilizer chamber, by design, is capable of well-defined physical characteristics. The hospital sterilizer system as configured after retrofit demonstrates equal or better performance.

Emission controls, whether or an integral part of the sterilizer or not, are accommodated in both predicate and H&W systems. (Amsco EO sterilizer, dependent on vintage, may or may not have the integral Envirogard® emission control system. Castle EO sterilizers employ external means for emission control.)

AAMI/ANSI ST24: Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities, 3rd edition, AAMI/ANSI, 1999 is the consensus standard to which the H&W system was designed for conformance. The predicate system was design to an earlier edition of the same standard. While not identical, because each edition reflects the then current thinking regarding the best practice at the time of revision, both predicate and H&W systems do reflect the same conformance to the state of the art regarding control systems at the time of their introduction. When allowance is made for that consideration, the two systems meet the same criteria for acceptance.

Safety

Mechanical Safety is assured in both the predicate and H&W systems by using the original equipment manufacturer or qualified third part remanufacturer to inspect and qualify the suitability of the vessel to meet the requirements of the ASME Boiler and Pressure Vessel Code referenced in the consensus standard. Further mechanical safety is assured be conformity to IEC 1010-2-042 requirements.

Electrical Safety is assured in the H&W system by conformance to IEC 1010-2-042 Particular Requirements for Toxic Gas Sterilizers. The predicate device met only the general electrical requirements of UL 3101-1 Part 1 for laboratory equipment. The IEC requirements are more comprehensive and specifically address all aspects of EO sterilizer safety as opposed to the more general and less stringent considerations for the broad category of laboratory equipment contained in the UL document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2003

Mr. Charles O. Hancock
Director, Regulatory Affairs
H & W Technologies, LLC
P.O. Box 20281
Rochester, New York 14602-0281

Re: K014013
Trade/Device Name: H & W Hospital Ethylene Oxide Sterilizer Control System
Regulation Number: 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: FLF
Dated: April 23, 2003
Received: April 25, 2003

Dear Mr. Hancock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K014013

Device Name H & W Hospital Ethylene Oxide Sterilizer Control System

Indications for Use The H & W Hospital Ethylene Oxide Sterilizer Control System is an accessory in the form of an electronic control system for the retrofit of existing sterilizers to provide operator and information monitoring capabilities of a personal computer (PC) together with the functional reliability, safety, and dependability of control obtained through the use of a programmable logic controller (PLC). The H & W Hospital Ethylene Oxide Sterilizer Control System is intended to retrofit existing Steris (Amsco) Eagle Model 2000 & 3000 series and Getinge (Castle) Model M/C 3500, 3600 or 4200 series Hospital EO Sterilizers only. The automated cycle performs in such a manner as to assure the repeatability of the process. The predetermined cycles duplicate the cycles provided by the original equipment manufacturer and are demonstrated to deliver the biological performance as stipulated in the consensus standard ANSI/AAMI ST-24.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K014013